



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Annual Computational Science Symposium; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA), in cosponsorship with the Pharmaceutical Users Software Exchange (PhUSE), is announcing a public conference entitled “The FDA/PhUSE Annual Computational Science Symposium.” The purpose of the conference is to help the broader community align and share experiences to advance computational science. At the conference, which will bring together FDA, industry, and academia, FDA will update participants on current initiatives, and collaborative working groups will address specific challenges in accessing and reviewing data to support product development. These working groups will focus on solutions and practical ways to implement them.

Date and Time: The public conference will be held on March 19 and 20, 2012, from 9 a.m. to 4:30 p.m.

Location: The public conference will be held at the Silver Spring Civic Building at Veterans Plaza, One Veterans Pl., Silver Spring, MD 20910, 1-240 777-5300.

Contact: Chris Decker, U.S. Regional Director, Pharmaceutical Users Software Exchange (PhUSE), 64 High St., BROADSTAIRS CT10 1JT, United Kingdom, 202-386-6722, email: office@phuse.eu.

SUPPLEMENTARY INFORMATION:

I. Working Groups and Their Areas of Focus

Six working groups will address particular challenges related to the access and review of data to support product development:

- Working Group 1: Data Validation and Quality Assessment,
- Working Group 2: Reducing Risk Within the Inspection Site Selection Process,
- Working Group 3: Challenges of Integrating and Converting Data Across Studies,
- Working Group 4: Standards Implementation Issues With the Clinical Data

Interchange Standards Consortium Data Models,

- Working Group 5: Development of Standard Scripts for Analysis and

Programming, and

- Working Group 6: “Non-Clinical Road-Map” and Impacts on Implementation.

A description of the planned activities of the working groups can be found at <http://www.phuse.eu/Working-Groups.aspx>. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

II. Registration and Accommodations

A. Registration

To register, please submit the registration form online at <https://www.phuse.eu/PhUSE-Conference-2012-Registration.aspx>. Registration fees cover the cost of facilities, materials, and food functions. Seats are limited, and conference space will be filled in the order in which registrations are received. Onsite registration will be available to the extent that space is

available on the day of the conference. The costs of registration for different categories of attendee are as follows:

Cost of Registration	
Category	Cost
Industry representatives registering by January 15, 2012	\$750
Industry representatives registering after January 15, 2012	\$950
Those with Government affiliation	\$300
Representatives of nonprofit organizations	\$600
Those attending for a single day	\$650

Government and nonprofit attendees and exhibitors will need an invitation code to register at the discounted rate. An invitation code can be obtained by sending an email to: office@phuse.eu. All registrants will pay a fee with the exception of a limited number of speakers/organizers who will have a complimentary registration.

B. Accommodations

Attendees are responsible for their own accommodations. Attendees making reservations at the Courtyard by Marriott Silver Spring Downtown Hotel are eligible for a reduced conference rate of \$199, not including applicable taxes. Those making reservations online should use the group code "SPRSPRB" to receive the special rate. If you need special accommodations because of disability, please contact Chris Decker (see Contact) at least 7 days before the meeting.

III. Posters and Exhibits Information

Posters will be presented and may include demonstrations to provide an interactive experience. Although PhUSE welcomes demonstrations to support and explore the posters that are presented, neither PhUSE nor FDA endorse any commercial software or vendor. The creator of what is judged the best poster will be recognized and offered the opportunity to present the poster at the closing session.

Poster topics include:

- Data submission standards development, implementation, and best practices;
- User experience and evaluation of current processes and tools and their effects on organizational performance;
- Needs and specifications for proposed new tools and processes;
- Business processes driving the development of information systems; and
- The effect of processes and tools on problem solving quality, efficiency, and cost.

Those interested in more information should refer to the PhUSE Web site at

<http://www.phuse.eu/ssc4p.aspxweb> .

The conference will make available an exhibition hall. The exhibitor price for this conference is \$3,500.

Dated: January 24, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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